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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,969	08/01/2001	Chantal Cayuela	33339/234602	5142

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

## Office Action Summary

Application No.

09/856,969

Applicant(s)

CAYUELA ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in Paper No. 8 is acknowledged.

The traversal is on the ground(s) that the technical relationship between the composition of Group I and the screening process of group II clearly constitute the common inventive concept which links the groups together. This is not found persuasive because they lack the same or corresponding special technical features. The process does not require the specific use of bacterial components moreover, the composition can be used with different types of method steps such as a method for regulating inflammatory response of enterocytes. Thus, the composition of group I and method of group II have a different special technical feature. Accordingly, the groups lack the same technical feature. The requirement is still deemed proper and is therefore made FINAL.

### ***Drawings***

2. The drawings are objected to because of the reasons set forth in the attached PTOL-948. However, the corrections will not be held in abeyance and applicant must submit proposed drawing corrections in response to the requirement in the Office action.

***Specification***

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 and 10-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition containing lactic acid bacteria strain, *L. casei* CNCM I-1518 in a dose dependant manner, further comprising inhibitors of NFkB transduction pathway or analogues of L-arginine that constitute competitive inhibitors specific for NO-synthase to decrease the production of nitric oxide by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial lipopolysaccharides on colon carcinoma cell lines does not reasonably provide enablement for a composition which regulates the inflammatory response of enterocytes containing as an active agent a lactic acid bacteria strain being capable of decreasing the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS. The specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are drawn to a composition which regulates the inflammatory response of enterocytes containing as an active agent a lactic acid bacteria strain being capable of decreasing the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS .

The specification teaches that *L. casei* alone has no effect on the production of NO on colon carcinoma cell lines (page 8 lines 26-27). The specification also teaches that the presence of CYTOMIX and *L. casei*, increases the production of NO in those same carcinoma cell lines (page 8 lines 20-25 and Figure 1). Figure 2 teaches an inhibition of NO production only occurs in the presence of competitive inhibitors specific for NO-synthase.

There is no teaching within the specification of composition without inhibitors of NFkB transduction pathway or analogues of L-arginine that constitute competitive inhibitors specific for NO-synthase to decrease the production of nitric oxide. The specification fails to teach examples compositions that meet the limitations of the claims in the manner instantly claimed. Therefore, the specification fails to enable both a composition and a method for production of said compositions that are capable of decreasing the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS.

Claim 2 is drawn to composition comprising a strain which must be capable of increasing the production of NO by cultures of enterocytes preactivated with pro-

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inflammatory cytokines and bacterial LPS. However, the specification clearly states that *L. casei* alone has no effect on the production of NO on colon carcinoma cell lines. The instant <sup>claims</sup> are drawn to a composition which only comprises the bacteria, therefore the composition alone will not regulate the inflammatory response of enterocytes. There is no teaching within the specification which teaches a composition comprised solely of the lactic acid bacteria which has the recited abilities. Therefore, the specification fails to enable said composition.

Applicants' have provided no guidance to enable one of ordinary skill in the art as to how determine, without undue experimentation, such compositions or method of producing said compositions. One of skill in the art would have to locate, de novo, active agents for said compositions and method of producing said composition as required by the instant claims.

Given the lack of guidance contained in the specification and the unpredictability for making and using the compositions and method of production, one of skill in the art could not make or use the broadly claimed invention without undue experimentation. There is no requirement or limitation for the composition to further comprise inhibitors of NF $\kappa$ B transduction pathway or analogues of L-arginine that constitute competitive inhibitors specific for NO-synthase to decrease the production of nitric oxide. In view of the lack of guidance contained in the specification and the unpredictability for the production of such composition and the composition, one skilled in the art could not make or use the broadly claimed invention without undue experimentation.

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5. Claims 1-6 and 10-20<sup>are</sup> rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites acronyms like NO and LPS must be spelled out when used for the first time in a chain of claims.

6. Claim 2 is unclear. It is unclear how the lactic acid bacteria strain comprised within the composition can be capable of decreasing the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS, as per claim 1 and also be capable of increasing the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS as per claim 2. Therefore, clarification is required to overcome the rejection.

7. Claim 4 recites the abbreviation *L.casei* which must be spelled out when used for the first time in a chain of claims.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 12-15 of US Patent 6,399,055 are drawn to a composition comprising an infant formula and a milk product fermented with a bacterial agent consisting essentially of *L. casei* DN114-001.

Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-15 of U.S. Patent No. 6,399,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims are drawn to a composition containing lactic acid bacteria, wherein the bacterial strain is *L. casei* strain CNCM I-1518 and the composition is in the form of a food supplement or fermented dairy product.

The instant specification teaches bacterial cultures from the Collection Nationale de Cultures de Microorganismes (CNCM) identified as DN-114001 a *Lactobacillus casei* strain which is the same strain and source used by the instant application renamed as CNCMI-1518. See the instant specification at page 2 lines 18-29.

Therefore, both the instant claims and patented claims are drawn to a composition containing a lactic acid bacterium, *L. casei* strain, in the form of a food supplement, infant formula or as a dairy (milk) product. It is noted that the function of the bacteria instantly claimed, does not change the structure of the composition, Thus, the compositions are not patentably distinct from each other since both the compositions comprise the same lactic acid bacterial strains.



**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 and 10-20<sup>are</sup> rejected under 35 U.S.C. 102(b) as being anticipated by Bouley et al., (WO 96/20607). Bouley et al., (WO 96/20607) teach a milk starter culture of a mixture of three lactic acid bacteria, *Streptococcus thermophilus* DN-001147, DN-001339 and *Lactobacillus bulgaricus* DN-100182 are disclosed (abstract). Fermented dairy food prepared by means of the starter culture and uses of the starter culture and fermented food products are also disclosed (abstract). The specification teaches the use of stock cultures from the Collection Nationale de Cultures de Microorganismes (CNCM) identified as DN-114001 *Lactobacillus casei* strain. This is the same strain and source used by the instant application renamed as CNCMI-1518. See the instant specification at page 2 lines 18-29.

The claimed composition invention does not result in a structural difference between the claimed invention and the prior art reference. The prior art composition is capable of performing the intended use of being capable of decreasing the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS, thus it meets the claims. A composition comprising the same active agent will inherently have the functional ability of being capable of decreasing the

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production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS. The intended use of the composition i.e., having the ability to decrease the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS does not change or affect the structural formation of the claims. Therefore the prior art reference teaches a composition comprising a lactic acid bacteria.

With respect to the method for producing a composition, the method comprises one active step, "formulating the composition" and the additional language of the claim describes the function of the composition and does not add additional method steps to the claims. Since the prior art and instant specification teach that the bacterial culture can be obtained from CNCM and formulated in a milk starter culture composition, then the prior art teaches the method for producing a composition wherein the active step of formulating a composition is met. Moreover, as previously discussed the composition comprising the same bacteria as disclosed by the instant claims will inherently have the same function.

11. Claims 1-2, 5 and 10-12 rejected under 35 U.S.C. 102(b) as being anticipated by Meinke (WO 88/00438). Meinke teaches medicinal substances or products containing lactic acid bacteria obtained from the fermentation of bread in water (abstract). The substances contain living lactic acid bacteria (abstract).

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It is noted that the claims are drawn to a composition whose sole ingredient is a lactic acid bacteria strain. Therefore the art teaches a composition comprising a lactic acid bacteria. Furthermore, any composition comprising the same active agent will inherently have the functional ability of being capable of decreasing the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS. The intended use of the composition i.e., having the ability to decrease the production of NO by cultures of enterocytes preactivated with pro-inflammatory cytokines and bacterial LPS does not change or affect the structural formation of the claims and thereby carries no additional patentable weight. The claimed invention does not result in a structural difference between the claimed invention and the prior art reference. The prior art composition is capable of performing the intended use, thus it meets the claims.

### ***Prior Art***


12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Krueger et al., (US Patent 6,444,203) teach administering a composition comprised of lactic acid bacteria. Menge (GB 2,126,071) teach fermenting dough comprising lactic acid bacteria.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines   
January 21, 2003

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
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